UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/501,359	07/15/2004	Domenico Fanara	2004_1045A	8158

513 7590 12/15/2006

WENDEROTH, LIND & PONACK, L.L.P.
2033 K STREET N. W.
SUITE 800
WASHINGTON, DC 20006-1021

EXAMINER	
ROBERTS, LEZAH	

ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 12/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

TH

Office Action Summary	Application No.	Applicant(s)	
	10/501,359	FANARA ET AL.	
	Examiner	Art Unit	
	Lezah W. Roberts	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-22 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-22 is/are rejected.

7)☒ Claim(s) 4 is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date A-C.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims

Claim Objections

Claim 4 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 4 recites the limitation "polyols having a molecular weight of less than 300", this limitation is already recited in the independent claim. The dependent claim does not further limit the independent claim.

Claim Rejections - 35 USC § 112 – Written Description

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-22 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The term "drug", while usually acceptable per se, lacks an adequate description as used herein. This is because the term "drug" is not

defined, and what is excluded by the proviso "any drug" is lacking an adequate written description. For example, xylitol (page 3, paragraph 0040) is a "drug", but is apparently permissible for inclusion in the instant claims. This can be obviated by amending the claims to clarify that the second formulation does not contain "a compound of formula I".

Claim Rejections - 35 USC § 112 - Indefiniteness

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Where applicant acts as his or her own lexicographer to specifically define a term of a claim contrary to its ordinary meaning, the written description must clearly redefine the claim term and set forth the uncommon definition so as to put one reasonably skilled in the art on notice that the applicant intended to so redefine that claim term. *Process Control Corp. v. HydReclaim Corp.*, 190 F.3d 1350, 1357, 52 USPQ2d 1029, 1033 (Fed. Cir. 1999). The term "any drug", as used in the specific context of the instant claims, is unclear in scope for the reasons given in the "Written Description" rejection above.

Claim Rejections - 35 USC § 102 - Anticipation

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

1) Claims 1-9, 12, 14-18 and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by Gowan (EP 0636,364).

Gowan discloses oral compositions comprising a compressed dosage form containing pharmaceutical particles coated with a taste-masking composition. The active or coated pharmaceuticals include cetirizine and pharmaceutically acceptable salts thereof, encompassing claim 14. The coating is a polymer blend and encompasses claim 17. The active comprises 5 to 90% of the coated particle and may also include binders and fillers when formulated into a granulated particle (page 6, lines 9-15), encompassing claim 12 and the limitations of mole ratio of the instant claims. The coated particle comprises 0.5 to 600 mg of the total compressed tablet. The coated active is then added to a blend of materials comprising mannitol, which is a compressible carbohydrate and may range from 250 to 750 mg, encompassing claim 22. The reference anticipates the claims insofar as it discloses a dosage form with two formulations, one comprising a compound of formula I and the other comprising a polyol.

2) Claims 1-8, 12-15, 19-20 and 22 are rejected under 35 U.S.C. 102(e) as being anticipated by Johnson et al. (US 6,627,234).

Johnson et al. disclose coated chewing gum compositions where the coating or the coating and gum center comprise an active agent (col. 2, lines 62-64). The active agents include cetirizine hydrochloride (col. 6, line 50), encompassing claim 14. Active agents are incorporated at weights ranging from 12 micrograms to 250 milligrams of gum including the core and base. Medicants may be dissolved in solvents, flavors and other transdermal vehicles. The coating also includes sweeteners such as sucrose, saccharin, saccharin salts, aspartame, sucralose and acesulfame-K, flavors and bitterness inhibitors such as sodium salts (col. 9, lines 24-32). Bulk sweeteners included in the chewing gum base include mannitol and comprise 5 to 95% of the gum (col. 12, lines 27-39). The coating may also be a film coating comprising the active agent. After the film is applied to the gum pellet, a polyol coating may be applied (col. 14, lines 23-35). These embodiments encompass claims 19-20. Coatings are usually made as syrups then dried. The reference anticipates the claims insofar as it discloses a chewing gum with two formulations, one comprising a compound of formula I and the other comprising a polyol with a molecular weight of less than 3000.

3) Claims 1-9, 12, 14-16 and 21-22 are rejected under 35 U.S.C. 102(b) as being anticipated by Fekete et al. (US 5,543,155).

Fekete et al. disclose multilayer tablets wherein one layer comprises an active agent and the other a hydrophilic polymer. The active agents include cetirizine. The

active layer may comprise tabletting fillers (such as e.g. cellulose, microcrystalline cellulose, lactose, mannitol, starch, dicalcium phosphate and the like), which, if desired, are then granulated in way known in the practice of tabletting, by using any of the processes described above. The other layer containing no active agent is prepared from a 2% solution of HPMC having a viscosity higher than 1000 cP alone or together with 0 to 70% by weight of tabletting filler (such as e.g. cellulose, microcrystalline cellulose, lactose, mannitol, starch, dicalcium phosphate and the like), which, if desired, are then granulated in way known in the practice of tabletting, by using any of the processes described above. Subsequently, two-layer tablets containing the required amount of active agent in one layer and the required amount of HPMC in the other one, are prepared from the powder mixture of two kinds or, if desired, from the granulates prepared therefrom, which the lubricants needed had separately been mixed to by applying the second tablet core layer to the first one (cols. 8-11). In regards to claim 21 wherein the compound is in the form of a dried syrup, Applicant defines dry syrup as "a solid formulation such as for example powder or granules destinated to be administered orally in this form or after addition to a liquid", which appears to be encompassed by a tablet. The reference anticipates the claims insofar as it discloses a tablet with two formulations, one comprising a compound of formula I and the other comprising a polyol.

Claim Rejections - 35 USC § 103 - Obviousness

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 10-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fekete et al. (US 5,543,155) in view of Fanara et al. (US 2004/0170690).

The primary reference, Fekete et al., is discussed above. The reference differs from the instant claims insofar as it does not disclose using sodium citrate in the multilayer tablet compositions.

Fanara et al. discloses multilayer tablets comprising cetirizine and its enatiomers in one layer and pseudoephedrine in a second layer. The compositions comprise sodium citrate as an alkalinizing agent that provides stability to the tablet (paragraph 0011). The reference differs from the instant claims insofar as it discloses a drug in the second formulation.

It is *prima facie* obviousness to select a known material based on its suitability for its intended use. *See Sinclair & Carroll Co. v. Interchemical Corp.*, 325 U.S. 327, 65 USPQ 297 (1945). Also, established precedent holds that it is generally obvious to add known ingredients to known compositions with the expectation of obtaining their known function. See, e.g., In re Linder, 457 F.2d 506, 507 (CCPA 1972); see also In re Dial, 326 F.2d 430, 432 (CCPA 1964). It would have been obvious to one of ordinary skill in the art to have used sodium citrate or another alkalinizing agent in the compositions of the primary reference for their known stability imparting function, as disclosed by the secondary reference and supported by cited precedent.

Claims 1-22 are rejected.

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lezah W. Roberts whose telephone number is 571-272-1071. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Lezah Roberts
Patent Examiner
Art Unit 1614

Frederick Krass
Primary Examiner
Art Unit 1614